IN THE UNITED STATES PATENTAND TRADEMARK OFFICE

Application No.:	09/806,125	Art Unit:	1642
Filed:	3/28/2001	Examiner:	Rawlings, S.
1st Inventor:	MATSUTANI, Eisuya	Allowed:	
For:	Agent that retards the transformation of hormone-dependent cancer to non-hormone dependent cancer	Batch:	
Atty. Dkt. No.	2556 US0P	Paper No.:	

Response to Notice to Comply with Sequence Listing Requirements

BOX SEQ
Commissioner for Patents
Washington, D.C. 20231
Sir:

In response to the Notice to Comply mailed April 7, 2003, Applicants respectfully submit, along with a copy of the Notice, a substitute written Sequence Listing and a replacement DOS Text CRF Sequence Listing file "2556SEQ.txt" on the enclosed 3.5" IBM PC/AT computer disk.

The undersigned hereby certifies that the CRF and the written Sequence Listing are the same in content. The Sequence Listing contains no new matter.

Respectfully submitted,

Dated: April 22, 2003

(847)383-3372
(847)383-3391

Mark Chao, Ph.D., Reg. No. 37,293
Elaine M. Ramesh, Ph.D., Reg. No. 43032
Attorney for Applicants
Customer No. 23115

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
Suite 500, 475 Half Day Road
Lincolnshire, IL 60069 USA

Notice to Comply	Application No. 09/806,125	Applicant(s) MATSUTANI ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1642	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

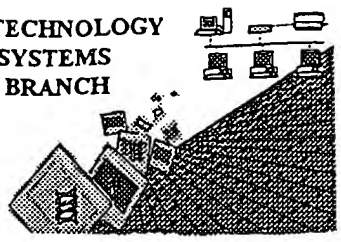
For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

Rawlings

MAY 01 2003

BIOTECHNOLOGY SYSTEMS BRANCH



RAW SEQUENCE LISTING ERROR REPORT

Re-RUN

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

RECEIVED

MAY 0 6 2003

TECH CENTER 1600/2900

Application Serial Number: 09/806,125B
Source: 1600
Date Processed by STIC: 3/12/2003

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

1) **INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,**
2) **TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY**

FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216.
PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax)
PATENTIN 3.0 e-mail help: patin3help@uspto.gov or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 3.1 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:
http://www.uspto.gov/web/offices/pac/checker

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.
Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.
Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<http://www.uspto.gov/ebc/efs/downloads/documents.htm> , **EFS Submission User Manual** - ePAVE)
2. **U.S. Postal Service:** U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202
3. **Hand Carry directly to:**
   U.S. Patent and Trademark Office, Technology Center 1600, Reception Area, 7th Floor, Examiner Name, Sequence Information, Crystal Mall One, 1911 South Clark Street, Arlington, VA 22202
   Or,
   U.S. Patent and Trademark Office, Box Sequence, Customer Window, Lobby, Room 1B03, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202
4. **Federal Express, United Parcel Service, or other delivery service to:** U.S. Patent and Trademark Office, Box Sequence, Room 1B03-Mailroom, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202

Revised 01/29/2002

Raw Sequence Listing Error Summary

ERROR DETECTED	SUGGESTED CORRECTION	SERIAL NUMBER: 09/806,125B

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

1	Wrapped Nucleics Wrapped Aminos	The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."
2	Invalid Line Length	The rules require that a line not exceed 72 characters in length. This includes white spaces.
3	Misaligned Amino Numbering	The numbering under each 5th amino acid is misaligned. Do not use tab codes between numbers; use space characters, instead.
4	Non-ASCII	The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.
5	Variable Length	Sequence(s)____contain n's or Xaa's representing more than one residue. Per Sequence Rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.
6	PatentIn 2.0 "bug"	A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequences(s) _____. Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
7	Skipped Sequences (OLD RULES)	Sequence(s) _____ missing. If intentional, please insert the following lines for each skipped sequence: (2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) (i) SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading) (xi) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) This sequence is intentionally skipped Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to include the skipped sequences.
8	Skipped Sequences (NEW RULES)	Sequence(s) _____ missing. If intentional, please insert the following lines for each skipped sequence. <210> sequence id number <400> sequence id number 000
9	Use of n's or Xaa's (NEW RULES)	Use of n's and/or Xaa's have been detected in the Sequence Listing. Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present. In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
10	Invalid <213> Response	Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or Artificial Sequence
11	Use of <220>	Sequence(s) _____ missing the <220> "Feature" and associated numeric identifiers and responses. Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section. (See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of Sequence Rules)
12	PatentIn 2.0 "bug"	Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.
13	Misuse of n	n can only be used to represent a single nucleotide in a nucleic acid sequence. N is not used to represent any value not specifically a nucleotide.

1600

RAW SEQUENCE LISTING DATE: 03/12/2003
PATENT APPLICATION: US/09/806,125B TIME: 13:55:58

Input Set : A:\2556usop.ST25.txt
Output Set: N:\CRF4\03122003\I806125B.raw

pp 1-3,

Insufficient Explanation

Does Not Comply
Corrected Diskette Needed

```
  3 <110> APPLICANT: MATSUTANI, Etsuya
  4       NAITO, Kenichiro
  6 <120> TITLE OF INVENTION: Agents For Retarding Change of Hormone-dependent Cancer into
  7       Hormone-independent Cancer
  9 <130> FILE REFERENCE: 2556USOP
 11 <140> CURRENT APPLICATION NUMBER: 09/806,125B
 12 <141> CURRENT FILING DATE: 2001-03-28
 14 <150> PRIOR APPLICATION NUMBER: PCT/JP99/05533
 15 <151> PRIOR FILING DATE: 1999-10-07
 17 <150> PRIOR APPLICATION NUMBER: JP 10-286793
 18 <151> PRIOR FILING DATE: 1998-10-08
 20 <160> NUMBER OF SEQ ID NOS: 13
 22 <170> SOFTWARE: PatentIn version 3.2
 24 <210> SEQ ID NO: 1
 25 <211> LENGTH: 10
 26 <212> TYPE: PRT
 27 <213> ORGANISM: artificial
 29 <220> FEATURE:
 30 <223> OTHER INFORMATION: peptide
 33 <220> FEATURE:
 34 <221> NAME/KEY: MISC_FEATURE
 35 <222> LOCATION: (6)..(6)
 36 <223> OTHER INFORMATION: D-Leu
 38 <220> FEATURE:
 39 <221> NAME/KEY: MISC_FEATURE
 40 <222> LOCATION: (10)..(10)
 41 <223> OTHER INFORMATION: -NH-C2H5
 43 <400> SEQUENCE: 1
W--> 45 Pro His Trp Ser Tyr Xaa Leu Arg Pro Xaa
 46 1               5                   10
 49 <210> SEQ ID NO: 2
 50 <211> LENGTH: 10
 51 <212> TYPE: PRT
 52 <213> ORGANISM: artificial
 54 <220> FEATURE:
 55 <223> OTHER INFORMATION: peptide
 58 <220> FEATURE:
 59 <221> NAME/KEY: MISC_FEATURE
 60 <222> LOCATION: (6)..(6)
 61 <223> OTHER INFORMATION: DLeu, DAla, DTrp, DSer(tBut), D2Nal, DHis(ImBzl)
 63 <220> FEATURE:
 64 <221> NAME/KEY: MISC_FEATURE
 65 <222> LOCATION: (10)..(10)
```

give source of genetic material (see item 11 on Error Summary Sheet)

FYI: Xaa can only represent a single amino acid, nothing else

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Xaa can only represent a single amino acid

Input Set : A:\2556usop.ST25.txt
Output Set: N:\CRF4\03122003\I806125B.raw

CK

66 <223> OTHER INFORMATION: NH-C2H5, Gly-NH2
68 <400> SEQUENCE: 2
W--> 70 **Pro His Trp Ser Tyr Xaa Leu Arg Pro Xaa**
71 1 5 10
74 <210> SEQ ID NO: 3
75 <211> LENGTH: 11
76 <212> TYPE: PRT
77 <213> ORGANISM: artificial
79 <220> FEATURE:
80 <223> OTHER INFORMATION: peptide
83 <220> FEATURE:
84 <221> NAME/KEY: MISC_FEATURE
85 <222> LOCATION: (1)..(1)
86 <223> OTHER INFORMATION: N(4H2-furoyl)Gly, NAc
88 <220> FEATURE:
89 <221> NAME/KEY: MISC_FEATURE
90 <222> LOCATION: (2)..(2)
91 <223> OTHER INFORMATION: D2Nal
93 <220> FEATURE:
94 <221> NAME/KEY: MISC_FEATURE
95 <222> LOCATION: (3)..(3)
96 <223> OTHER INFORMATION: D4ClPhe
98 <220> FEATURE:
99 <221> NAME/KEY: MISC_FEATURE
100 <222> LOCATION: (4)..(4)
101 <223> OTHER INFORMATION: D3Pal
103 <220> FEATURE:
104 <221> NAME/KEY: MISC_FEATURE
105 <222> LOCATION: (6)..(6)
106 <223> OTHER INFORMATION: NMeTyr, Tyr, Aph(Atz), NMeAph(Atz)
108 <220> FEATURE:
109 <221> NAME/KEY: MISC_FEATURE
110 <222> LOCATION: (7)..(7)
111 <223> OTHER INFORMATION: DLys(Nisp), DCit, DLys(AzaglyNic), DLys(AzaglyFur), DhArg (Atz),
112 DhCi
114 <220> FEATURE:
115 <221> NAME/KEY: MISC_FEATURE
116 <222> LOCATION: (9)..(9)
117 <223> OTHER INFORMATION: Lys(Nisp), Arg, hArg(Et2)
119 <220> FEATURE:
120 <221> NAME/KEY: MISC_FEATURE
121 <222> LOCATION: (11)..(11)
122 <223> OTHER INFORMATION: DAla
124 <400> SEQUENCE: 3
W--> 126 **Xaa Xaa Xaa Xaa Ser Xaa Xaa Leu Xaa Pro Xaa**
127 1 5 10
130 <210> SEQ ID NO: 4
131 <211> LENGTH: 6
132 <212> TYPE: PRT

RAW SEQUENCE LISTING
PATENT APPLICATION: US/09/806,125B

DATE: 03/12/2003
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Input Set : A:\2556usop.ST25.txt
Output Set: N:\CRF4\03122003\I806125B.raw

133 <213> ORGANISM: artificial
135 <220> FEATURE:
136 <223> OTHER INFORMATION: peptide
138 <400> SEQUENCE: 4
140 His Arg Asp Leu Ala Ala
141 1 5
144 <210> SEQ ID NO: 5
145 <211> LENGTH: 5
146 <212> TYPE: PRT
147 <213> ORGANISM: artificial
149 <220> FEATURE:
150 <223> OTHER INFORMATION: peptide
152 <400> SEQUENCE: 5
154 Ser Asp Val Trp Ser
155 1 5
158 <210> SEQ ID NO: 6
159 <211> LENGTH: 16
160 <212> TYPE: DNA
161 <213> ORGANISM: artificial
163 <220> FEATURE:
164 <223> OTHER INFORMATION: primer
167 <220> FEATURE:
168 <221> NAME/KEY: misc_feature
169 <222> LOCATION: (3)..(3)
170 <223> OTHER INFORMATION: C or T
172 <220> FEATURE:
173 <221> NAME/KEY: misc_feature
174 <222> LOCATION: (4)..(4)
175 <223> OTHER INFORMATION: C or A
177 <220> FEATURE:
178 <221> NAME/KEY: misc_feature
179 <222> LOCATION: (9)..(10)
180 <223> OTHER INFORMATION: C or T
182 <400> SEQUENCE: 6
W--> 183 cannggann ggcbgc 16
186 <210> SEQ ID NO: 7
187 <211> LENGTH: 16
188 <212> TYPE: DNA
189 <213> ORGANISM: artificial
191 <220> FEATURE:
192 <223> OTHER INFORMATION: primer
195 <220> FEATURE:
196 <221> NAME/KEY: misc_feature
197 <222> LOCATION: (2)..(2)
198 <223> OTHER INFORMATION: a or g
200 <220> FEATURE:
201 <221> NAME/KEY: misc_feature
202 <222> LOCATION: (8)..(8)
203 <223> OTHER INFORMATION: c or a

RAW SEQUENCE LISTING DATE: 03/12/2003
PATENT APPLICATION: US/09/806,125B TIME: 13:55:58

Input Set : A:\2556usop.ST25.txt
Output Set: N:\CRF4\03122003\I806125B.raw

205 <220> FEATURE:
206 <221> NAME/KEY: misc_feature
207 <222> LOCATION: (11)..(11)
208 <223> OTHER INFORMATION: g or a
210 <220> FEATURE:
211 <221> NAME/KEY: misc_feature
212 <222> LOCATION: (14)..(14)
213 <223> OTHER INFORMATION: a or g
215 <400> SEQUENCE: 7
W--> 216 anctccanac ntcnct 16
219 <210> SEQ ID NO: 8
220 <211> LENGTH: 17
221 <212> TYPE: DNA
222 <213> ORGANISM: artificial
224 <220> FEATURE:
225 <223> OTHER INFORMATION: primer
228 <220> FEATURE:
229 <221> NAME/KEY: misc_feature
230 <222> LOCATION: (3)..(3)
231 <223> OTHER INFORMATION: c or t
233 <220> FEATURE:
234 <221> NAME/KEY: misc_feature
235 <222> LOCATION: (4)..(4)
236 <223> OTHER INFORMATION: c or a
238 <220> FEATURE:
239 <221> NAME/KEY: misc_feature
240 <222> LOCATION: (6)..(6)
241 <223> OTHER INFORMATION: g or a
243 <220> FEATURE:
244 <221> NAME/KEY: misc_feature
245 <222> LOCATION: (10)..(10)
246 <223> OTHER INFORMATION: c or t
248 <220> FEATURE:
249 <221> NAME/KEY: misc_feature
250 <222> LOCATION: (12)..(12)
251 <223> OTHER INFORMATION: g or t
253 <220> FEATURE:
254 <221> NAME/KEY: misc_feature
255 <222> LOCATION: (15)..(15)
256 <223> OTHER INFORMATION: a or t
258 <400> SEQUENCE: 8
W--> 259 canngngacn tngcngc 17
262 <210> SEQ ID NO: 9
263 <211> LENGTH: 16
264 <212> TYPE: DNA
265 <213> ORGANISM: artificial
267 <220> FEATURE:
268 <223> OTHER INFORMATION: primer
271 <220> FEATURE:

RAW SEQUENCE LISTING DATE: 03/12/2003
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Input Set : A:\2556usop.ST25.txt
Output Set: N:\CRF4\03122003\I806125B.raw

272 <221> NAME/KEY: misc_feature
273 <222> LOCATION: (2)..(2)
274 <223> OTHER INFORMATION: a or g
276 <220> FEATURE:
277 <221> NAME/KEY: misc_feature
278 <222> LOCATION: (8)..(8)
279 <223> OTHER INFORMATION: a or c
281 <220> FEATURE:
282 <221> NAME/KEY: misc_feature
283 <222> LOCATION: (14)..(14)
284 <223> OTHER INFORMATION: a or c
286 <400> SEQUENCE: 9
W--> 287 anctccanac gtcnga 16
290 <210> SEQ ID NO: 10
291 <211> LENGTH: 17
292 <212> TYPE: DNA
293 <213> ORGANISM: artificial
295 <220> FEATURE:
296 <223> OTHER INFORMATION: primer
299 <220> FEATURE:
300 <221> NAME/KEY: misc_feature
301 <222> LOCATION: (3)..(3)
302 <223> OTHER INFORMATION: c or t
304 <220> FEATURE:
305 <221> NAME/KEY: misc_feature
306 <222> LOCATION: (4)..(4)
307 <223> OTHER INFORMATION: c or a
309 <220> FEATURE:
310 <221> NAME/KEY: misc_feature
311 <222> LOCATION: (6)..(6)
312 <223> OTHER INFORMATION: g or a
314 <220> FEATURE:
315 <221> NAME/KEY: misc_feature
316 <222> LOCATION: (10)..(10)
317 <223> OTHER INFORMATION: c or t
319 <220> FEATURE:
320 <221> NAME/KEY: misc_feature
321 <222> LOCATION: (15)..(15)
322 <223> OTHER INFORMATION: a or g
324 <400> SEQUENCE: 10
W--> 325 canngngacn tggcngc 17
328 <210> SEQ ID NO: 11
329 <211> LENGTH: 16
330 <212> TYPE: DNA
331 <213> ORGANISM: artificial
333 <220> FEATURE:
334 <223> OTHER INFORMATION: primer
337 <220> FEATURE:
338 <221> NAME/KEY: misc_feature

RAW SEQUENCE LISTING ERROR SUMMARY DATE: 03/12/2003
PATENT APPLICATION: US/09/806,125B TIME: 13:55:59

Input Set : A:\2556usop.ST25.txt
Output Set: N:\CRF4\03122003\I806125B.raw

Please Note:
Use of n and/or Xaa have been detected in the Sequence Listing. Please review the Sequence Listing to ensure that a corresponding explanation is presented in the <220> to <223> fields of each sequence which presents at least one n or Xaa.

Seq#:1; Xaa Pos. 6,10
Seq#:2; Xaa Pos. 6,16
Seq#:3; Xaa Pos. 1,2,3,4,6,7,9,11
Seq#:6; N Pos. 3,4,9,10
Seq#:7; N Pos. 2,8,11,14
Seq#:8; N Pos. 3,4,6,10,12,15
Seq#:9; N Pos. 2,8,14
Seq#:10; N Pos. 3,4,6,10,15
Seq#:11; N Pos. 2,8,11,14

Invalid <213> Response:
Use of "Artificial" only as "<213> Organism" response is incomplete, per 1.823(b) of New Sequence Rules. Valid response is Artificial Sequence.

Seq#:1,2,3,4,5,6,7,8,9,10,11,12,13